

January 13, 2005

CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 05-02

Subject: Issuance of Licenses

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS

The purpose of this notice is to bring to the attention of interested parties licenses issued and terminated during the months of October, November, and December 2004. These do not include those licenses reissued to update pertinent information. A product license or permit for distribution and sale has been issued for each of the following:

True Name	Product Code	Establishment/ Permittee	Date
Autogenous Vaccine, Killed Virus	1015.B0	SolidTech Animal Health, Inc., Est. 604	10/28/04
Autogenous Vaccine, Killed Virus	1015.I0	SolidTech Animal Health, Inc., Est. 604	10/28/04
Equine Rhinopneumonitis-Influenza Vaccine, Killed Virus	1515.23	Intervet Inc., Est. 286	12/22/04
Equine Rhinopneumonitis Vaccine, Killed Virus	1525.22	Intervet Inc., Est. 286	12/22/04
Erysipelothrix Rhusiopathiae Vaccine, Avirulent Live Culture	1541.04	ARKO Laboratories, Ltd., Est. 337	11/30/04
Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus	1651.05	Intervet Inc., Est. 286	12/10/04
Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus	16L1.08	Intervet Inc., Est. 286	12/17/04
Marek's Disease Vaccine, Serotype 1, Live Virus	16L1.09	Intervet Inc., Est. 286	12/10/04
Bursal Disease-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector	1A88.R0	Merial Select, Inc., Est. 279	11/23/04
Salmonella Newport Bacterial Extract	2811.00	Epitopix, LLC, Est. 365	11/3/04
Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin	2665.06	Novartis Animal Health US, Inc., Est. 303	11/22/04
Erysipelothrix Rhusiopathiae-Mycoplasma Hyopneumoniae Bacterin	2A41.00	Schering-Plough Animal Health Corp., Ext. 165A	12/10/04

True Name	Product Code	Establishment/ Permittee	Date
West Nile Virus Antibody, Equine Origin	3995.00	Colorado Serum Co., Est. 188	11/18/04
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.B0	SolidTech Animal Health, Inc., Est. 604	10/28/04
Autogenous Vaccine, Killed Virus, Autogenous Bacterin	4500.I0	SolidTech Animal Health, Inc., Est. 604	10/28/04
Encephalomyelitis-Rhinopneumonitis-Influenza Vaccine, Eastern and Western, Killed Virus, Tetanus Toxoid	4845.32	Intervet Inc., Est. 286	12/22/04
Renibacterium Salmoninarum Antigen Test Kit, ELISA	5800.20	Stolle Milk Biologics, Inc., Est. 633	10/25/04
Renibacterium Salmoninarum Antigen Test Kit, ELISA	5800.21	Stole Milk Biologics, Inc., Est. 633	10/25/04
Crotalus Atrox Toxoid	8900.00	Hygieia Biological Laboratories, Est. 407	11/19/04
Autogenous Virus, Killed Virus	A015.20	Newport Laboratories, Inc., Est. 455	10/28/04
Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona, Killed Culture	B668.00	Heska Corp., Est. 213	11/22/04
Autogenous Virus, Killed Virus, Autogenous Killed Culture	D500.20	Newport Laboratories, Inc., Est. 455	10/28/04

U.S. Veterinary Biologics Establishment License No. 633 was issued on October 25, 2004, to the following:

Stolle Milk Biologics, Inc.
6954 Cornell Road, Suite 400
Cincinnati, Ohio 45242-3025
MAIL: Stolle Milk Biologics, Inc.
6954 Cornell Road, Suite 400
Cincinnati, Ohio 45242-3025

The following product licenses for Pfizer Inc., Est. 189, were terminated without prejudice on December 31, 2004:

Feline Leukemia Vaccine, Killed Virus, Code 1555.22

Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Killed Virus,
Code 16D5.21

Mannheimia Haemolytica-Pasteurella Multocida Vaccine, Avirulent Live Culture,
Code 1861.00

Salmonella Choleraesuis Vaccine, Avirulent Live Culture, Code 19A1.00

Parvovirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Hardjo-
Icterohaemorrhagiae-Pomona Bacterin, Code 4975.21

The following product licenses for Merial, Inc., Est. 298, were terminated without prejudice on November 23, 2004:

Feline Leukemia Vaccine, Killed Virus, Code 1555.20

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci
Vaccine, Modified Live Virus and Chlamydia and Killed Virus, Code 1559.2B

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live
and Killed Virus, Code 15B9.20

Feline Leukemia-Rabies Vaccine, Killed Virus and Live Canarypox Vector
Code 15R5.R0

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Chlamydia Psittaci-
Rabies Vaccine, Modified Live Virus and Chlamydia and Killed Virus,
Canarypox Vector, Code 16A9.R0

Feline Leukemia-Rhinotracheitis-Calici-Panleukopenia-Rabies Vaccine, Modified
Live Virus and Killed Virus, Canarypox Vector, Code 16S9.R0

The following product licenses for Novartis Animal Health US, Inc., Est. 303, were terminated without prejudice on November 23, 2004:

Autogenous Vaccine, Killed Virus, Code 1015.00

Autogenous Vaccine, Killed Virus, Code 1015.01

Autogenous Vaccine, Killed Protozoa, Code 1016.00

Autogenous Bacterin, Code 2051.01

Autogenous Vaccine, Killed Virus, Autogenous Bacterin, Code 4500.01

The following product license for IDEXX Corporation, Est. 313, was terminated without prejudice on November 9, 2004:

Pseudorabies Virus gpI Antibody Test Kit, Code 5113.01

The following product license for Mr. Jerry L. Zinn, Permittee 335, was terminated without prejudice on October 26, 2004:

Vibrio Anguillarum-Ordalii Bacterin, Code 2858.02

The following product license for PanBio InDx, Inc., Est. 477, was terminated without prejudice on November 9, 2004:

Canine Borrelia Burgdorferi-Ehrlichia Canis-Rickettsia Rickettsii Antibody Test Kit, Code 5019.00

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics